

REMARKS

Upon entry of the amendments presented, claims 1 and 3-6 remain in the application. Claim 2 and claims 7-43 (non elected claims) have been cancelled, without prejudice. Claim 1 has been amended to recite the administration of a liquid composition, support for which can be found throughout Applicant's specification, including at page 4, paragraph 3.

Invention Synopsis

The method of the present invention is based upon the discovery that N-acetyl L-glutamine has utility as an oral glutamine supplement in humans. It has now been found that human intestinal tissue deacetylates N-acetyl-L-glutamine, to thus form glutamine for use in the body. As such, N-acetyl-L-glutamine can now be incorporated into oral nutritionals designed for human consumption to thus provide a source of supplemental glutamine. This is especially useful in liquid formulations where N-acetyl-L-glutamine is more stable than free glutamine. Free glutamine is more commonly used in solid or powder product forms.

Inventorship Correction

Inventorship correction is respectfully requested under 37 CFR 1.48(b) upon cancellation of claims 7-43 (non elected claims) from the present application. Since Jeffrey H. Baxter is the sole inventor of remaining claims 1 and 3-6, please delete Jose Maria Lopez and Ricardo Rueda as named inventors.

Rejection under 35 USC 102

Claims 1 and 6 have been rejected under 35 USC 102(b) as anticipated by JP 10101576. Applicant respectfully traverses this rejection, as it would apply to the amended claims.

This particular reference discloses compositions comprising glutamine (or derivatives) in combination with glicentin to treat digestive organ diseases. Also disclosed are compressed tablets comprising glicentin and acetyl glutamine (see paragraph 0027). This reference fails, however, to disclose any liquid compositions comprising N-acetyl-L-glutamine.

Applicant respectfully submits that this reference fails to disclose each and every limitation to which Claim 1 of the present application is now limited. In particular, Claim 1 is now directed to the administration of liquid compositions comprising N-acetyl-L-glutamine, whereas the JP reference fails to disclose any liquid formulation containing N-acetyl-L-acetyl glutamine, and therefore fails to disclose any methods of administering such a formulation.

In view of the amendments presented and the foregoing remarks, Applicant respectfully requests withdrawal of this rejection as it would apply to the remaining claims.

Rejection under 35 USC 103

Claims 1-6 have been rejected under 35 USC 103(a) as unpatentable over US 5,462,924 (Kihlberg) in view of US 4,994,457 (Crawford). In setting forth this rejection, the Examiner contends that it would have been obvious to administer oral glutamine as taught by Kihlberg, using either sodium or potassium salts of glutamine (oral) as taught by Crawford, to thereby realize Applicant's invention. Applicant respectfully traverses this rejection, as it would apply to the amended claims.

Applicant respectfully submits that this rejection is based upon an incorrect reading of the Crawford reference. In setting forth this rejection, the Examiner states:

"US '457 is relied upon for the solely teaching of the sodium and potassium salts of glutamine to be known in the art as acceptable salts for oral administration (col. 2, lines 44-46). Therefore, US '457 teaches the missing teaching from US '924, which is the salts of glutamine."

The Crawford reference, however, actually discloses at column 2, lines 44-46, the sodium and potassium salts of N-acetyl-L-methionine, not the salts of glutamine or N-acetylglutamine as suggested by the Examiner.

Crawford does teach, however, the use of aluminum salts (of either N-acetyl-L-glutamine or N-acetyl-L-carnosine) to treat drug-induced gastric ulcers in mice (col. 1, lines 67-68; col. 2, lines 1-4). It is also well known, however, that aluminum-containing materials (e.g., sulcrafate or sucrose aluminum sulfate, aluminum hydroxide, magnesium aluminum hydroxide) are commonly used in individuals afflicted with gastric ulcers. Nowhere does Crawford suggest that these aluminum salts can also be used as a supplemental form of glutamine in humans.

Crawford is also silent as to whether or not its aluminum salts (of either N-acetyl-L-glutamine or N-acetyl-L-carnosine) are administered as solids or liquids, orally or intravenously. In short, Crawford fails to suggest the use of oral liquids comprising N-acetyl-L-glutamine or salts thereof.

Neither reference, taken together or separately, discloses or suggests Applicant's method of providing glutamine supplementation to a human by administering an oral liquid comprising N-acetyl L-glutamine (or nutritionally acceptable salt). Kihlberg teaches oral administration of free glutamine, not N-acetyl L-glutamine. And Crawford teaches oral administration of aluminum salts (of either N-acetyl-L-glutamine or N-acetyl-L-carnosine) to prevent exacerbation of drug-induced gastric ulcers in rats (see column 1, lines 37-68 and column 2, lines 1-4), not to provide a glutamine supplement.

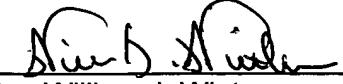
Even if there were some suggestion to combine the Crawford and Kihlberg references, such a combination would still not result in a realization of the present invention. The skilled artisan might consider an intravenous formulation from Kihlberg with Crawford's aluminum salts of N-acetyl-L-glutamine. But the contrived formula would still be intravenous, because there's no suggestion by Crawford to use the aluminum salts in an oral formulation, let alone an oral liquid formulation such as that to which the present claims are now limited. Although Kihlberg refers briefly to oral control formulas, this particular reference taken as a whole is clearly directed to intravenous rather than oral formulas.

In view of the amendments presented and the foregoing remarks, Applicant respectfully requests withdrawal of this rejection as it would apply to the remaining claims.

Conclusion

Applicant respectfully requests reconsideration of this application and allowance of claims 1 and 3-6.

Respectfully submitted,


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